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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

KING PHARMACEUTICALS, INC. and MERIDIAN MEDICAL TECHNOLOGIES, INC., Plaintiffs, v. SANDOZ INC., Defendant.	Civil Action No. 10-03568 (MLC) (LHG) **ANSWER AND COUNTERCLAIMS**

Defendant Sandoz Inc. ("Sandoz") answers the Complaint of King Pharmaceuticals, Inc. ("King Pharmaceuticals") and Meridian Medical Technologies, Inc. ("Meridian") (collectively "Plaintiffs") as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendant Sandoz's filing of Abbreviated New Drug Application ("ANDA") No. 090725 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff Meridian's highly successful EpiPen® Auto-Injector prior to the September 11, 2025 expiration of U.S. Patent No. 7,449,012 B2.

ANSWER: Sandoz admits that Plaintiffs' Complaint is for patent infringement of U.S. Patent No. 7,449,012 B2 ("the '012 patent") under the patent laws of the United States, but denies that Plaintiffs are entitled to such relief. Sandoz admits that it filed Abbreviated New Drug Application ("ANDA") No. 090725 with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell Sandoz's epinephrine injection in 0.3 mg/0.3 mL and 0.15 mg/0.3 mL dosage strengths ("Sandoz's ANDA product") prior to the expiration of the '012 patent. Sandoz admits that the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluation* (the "Orange Book") states that the '012 patent will expire on September 11, 2025. Sandoz denies any remaining allegations of paragraph 1.

THE PARTIES

2. Plaintiff King Pharmaceuticals is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. King Pharmaceuticals is in the business of developing, manufacturing, and bringing innovative medicines and technologies to market, primarily in specialty-driven markets including neuroscience and acute care medicines.

ANSWER: On information and belief, Sandoz admits that King Pharmaceuticals is a Tennessee corporation with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 2 and therefore denies those allegations.

3. Plaintiff Meridian is a Delaware corporation with its principal place of business at 10240 Old Columbia Road, Columbia, Maryland 21046. Meridian is a wholly-owned subsidiary of King Pharmaceuticals.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 3 and therefore denies those allegations.

4. Meridian is the holder of approved New Drug Application No. 019-430, and markets the product which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg ("EpiPen® Auto-Injector") pursuant to this NDA. On July 17, 2009, as required by the Federal Food, Drug, and Cosmetic Act ("FFDCA") and FDA regulations, Meridian submitted information concerning the '012 patent for listing in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly referred to as the "Orange Book." Meridian developed and manufactures the EpiPen® Auto-Injector, an easy-to-use, disposable drug delivery system featuring spring activation and a concealed needle. The EpiPen® Auto-Injector is sold throughout the United States and worldwide.

ANSWER: Sandoz admits that, on the FDA's website, Meridian is listed as the holder of approved New Drug Application ("NDA") No. 019-430 for EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg, sold under the name EpiPen® Auto-Injector. Sandoz further admits that the '012 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations,* commonly referred to as the "Orange Book." Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 4 and therefore denies those allegations.

5. Upon information and belief, Defendant Sandoz is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, U.S.A. Upon information and belief, Sandoz develops and markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of New Jersey.

ANSWER: Sandoz admits that it is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540, U.S.A. Sandoz further admits that it develops and markets a wide range of generic drug products. Sandoz denies any remaining allegations of paragraph 5.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America. This court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER: Paragraph 6 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz admits that this Court has subject matter jurisdiction over Counts I-II of Plaintiff's Complaint pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Sandoz denies any remaining allegations of paragraph 6.

7. This court has personal jurisdiction over Sandoz because, among other things, Sandoz's principal place of business is in New Jersey. By virtue of Sandoz's presence and regular and continuous business in the State of New Jersey, Sandoz has submitted itself to the personal jurisdiction of the courts in New Jersey.

ANSWER: Paragraph 7 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz admits that it has a principal place of business in New Jersey. Sandoz further admits that this Court has personal jurisdiction over it for the purposes of this action. Sandoz denies any remaining allegations of paragraph 7.

8. This Court also has personal jurisdiction over the Defendant by virtue of the fact that, among other things, Sandoz has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, which manufacture numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over the Defendant for the additional reasons set for [sic] below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Paragraph 8 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz admits that this Court has personal jurisdiction over it for the purposes of this action. Sandoz denies any remaining allegations of paragraph 8.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and 1400(b).

ANSWER: Paragraph 9 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz admits that venue is proper in this District under 28 U.S.C. § 1391(c). Sandoz denies that venue is proper in this District under 28 U.S.C. § 1400(b) because Sandoz has not committed acts of patent infringement in this District.

BACKGROUND

10. The EpiPen® Auto-Injector is designed for assisted- or self-administration of epinephrine in acute allergic emergencies (anaphylaxis), by providing a rapid, convenient dose of epinephrine for individuals needing protection from potentially fatal allergic reactions.

ANSWER: Sandoz admits that the approved label for the EpiPen® Auto-Injector states that the EpiPen® Auto-Injector is intended for immediate administration in patients, who are determined to be at increased risk for anaphylaxis. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 10 and therefore denies those allegations.

11. Meridian developed and manufactures the EpiPen® Auto-Injector pursuant to New Drug Application No. 019-430, which was approved by FDA.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about the truth of the allegations of paragraph 11 and therefore denies those allegations.

12. United States Patent No. 7,449,012 B2 ("the '012 patent"), entitled "Automatic Injector" was duly and legally issued by the U.S. Patent and Trademark Office on November 11, 2008. The '012 patent, owned by Meridian, will expire on September 11, 2025. A copy of the '012 patent is attached hereto as Exhibit A.

ANSWER: Sandoz admits that U.S. Patent No. 7,449,012 B2 ("the '012 patent") is entitled "Automatic Injector" and was issued by the U.S. Patent and Trademark Office on November 11, 2008. Sandoz further admits that Meridian is listed as the assignee on the face of the '012 patent and that, according to the Orange Book, the '012 patent will expire on September

11, 2025, which assumes that all required maintenance fees will be paid. Sandoz further admits that a copy of the '012 patent is attached as Exhibit A to Plaintiffs' Complaint. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 12 and therefore denies those allegations.

13. The EpiPen® Auto-Injector is covered by one or more claims of the '012 patent, and as such, the '012 patent was listed in connection with the EpiPen® Auto-Injector in FDA's Orange Book.

ANSWER: Sandoz admits that the '012 patent was listed in the FDA's Orange Book in connection with NDA No. 019-430. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 13 and therefore denies those allegations.

14. Upon information and belief, Sandoz submitted ANDA No. 090725 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of the EpiPen® Auto-Injector prior to the expiration of Meridian's '012 patent.

ANSWER: Sandoz admits that it submitted ANDA No. 090725 under 21 U.S.C. § 355(j)(2) seeking FDA approval to engage in the commercial manufacture, use, and/or sale of Sandoz's ANDA product prior to the expiration date of the '012 patent listed in the Orange Book. Sandoz denies any remaining allegations of paragraph 14.

15. By letter dated June 3, 2010, Sandoz notified Plaintiffs that Sandoz had submitted and FDA had received ANDA No. 090725 concerning Sandoz's proposed drug product, epinephrine injection 0.3mg/0.3 mL and 0.15/0.3 mL ("Sandoz's ANDA product"), as required by § 505(j)(2)(B)(i) and (ii) of the FFDCA. *See* 21 U.S.C. § 355(j)(2)(B)(i)–(ii).

ANSWER: Sandoz admits that by letter dated June 3, 2010, Sandoz notified Plaintiffs that Sandoz had submitted and the FDA had received ANDA No. 090725 concerning Sandoz's proposed drug product, epinephrine injection 0.3 mg/0.3 mL and 0.15 mg/0.3 mL ("Sandoz's ANDA product"), as required by 21 U.S.C. § 355(j)(2)(B)(i) and/or (ii) (Sections 505(j)(2)(B)(i)

and/or (ii) of the Federal Food, Drug and Cosmetics Act ("FFDCA")). Sandoz denies any remaining allegations of paragraph 15.

16. Sandoz's June 3 letter also notified Plaintiffs that, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, Sandoz filed with FDA a paragraph IV certification with respect to the '012 patent, alleging that the claims of the '012 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Sandoz's ANDA product. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

ANSWER: Sandoz admits that its letter of June 3, 2010 (the "June 3 letter") notified Plaintiffs that, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), Sandoz filed with the FDA a Paragraph IV certification that the '012 patent claims are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale, or offer for sale of Sandoz's ANDA product. Sandoz denies any remaining allegations of paragraph 16.

17. Sandoz's submission of ANDA No. 090725 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA product before the expiration of the '012 patent constitutes an act of infringement of one or more claims of the '012 patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Denied.

18. Plaintiffs received Sandoz's June 3 letter on or about June 8, 2010.

ANSWER: Admitted.

19. In accordance with the contact information Sandoz provided in its June 3 letter, Plaintiffs contacted Mr. Stephen R. Auten, Esq. ("Mr. Auten") by email on June 11, 2010, in order to gain access to Sandoz's ANDA and to address the terms of Sandoz's Offer of Confidential Access ("OCA"). Sandoz did not reply to this correspondence.

ANSWER: Sandoz admits that its June 3 letter included contact information for Mr. Auten and terms for gaining access to ANDA No. 090725 under the OCA. Sandoz lacks knowledge or information sufficient to form a belief about whether Mr. Auten received the June 11 email, which was not sent in accordance in with the information provided in Sandoz's June 3 letter. Therefore, Sandoz denies any remaining allegations of paragraph 19.

20. Plaintiffs again contacted Mr. Auten by email on June 18, 2010, requesting access to Sandoz's ANDA. Again, Sandoz did not reply.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about whether Mr. Auten received the June 18 email, which was not sent in accordance with the information provided in Sandoz's June 3 letter, and therefore denies the allegations of paragraph 20.

21. Plaintiffs contacted Mr. Auten a third time by email on June 25, 2010. Plaintiffs again requested immediate access to Sandoz's ANDA. Sandoz did not reply to this email.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about whether Mr. Auten received the June 25 email, which was not sent in accordance in with the information provided in Sandoz's June 3 letter, and therefore denies the allegations of paragraph 21.

22. On July 2, 2010, Plaintiffs sent Mr. Auten a letter via Federal Express, reiterating their request for Sandoz's ANDA and attaching a copy of all prior email correspondence. As confirmed by Federal Express, delivery of this letter to Sandoz occurred on July 6, 2010. To date, Sandoz has not responded to the July 2 letter.

ANSWER: Sandoz admits that it did not reply to Plaintiffs' July 2 letter, which was received on July 6 and which included OCA terms different from Sandoz's June 3 letter. Sandoz denies any remaining allegations of paragraph 22.

23. To date, Sandoz has not replied to any one of Plaintiffs' several attempts to gain access to Sandoz's ANDA.

ANSWER: Sandoz lacks knowledge or information sufficient to form a belief about Plaintiffs' attempts to gain access to Sandoz's ANDA under terms different from those set forth in Sandoz's June 3 letter, and therefore denies the allegations of paragraph 23.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 7,449,012 B2

24. Plaintiffs reallege and incorporate by reference paragraphs 1–23, above.

ANSWER: Sandoz repeats and incorporates its responses to paragraphs 1 through 23 above as if set forth fully herein.

25. Meridian is the owner by assignment of the '012 patent and has the right to sue for infringement thereof.

ANSWER: Sandoz admits that Meridian is listed as the assignee on the face of the '012 patent. Sandoz lacks knowledge or information sufficient to form a belief about the truth of the remaining allegations of paragraph 25 and therefore denies those allegations.

26. Upon information and belief, Sandoz's ANDA product, when offered for sale, sold, and/or imported, and then used as directed, would be used in a manner that would directly infringe one or more of the claims of the '012 patent.

ANSWER: Paragraph 26 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 26.

27. Upon information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA product would infringe one or more claims of the '012 patent. *See* 35 U.S.C. § 271(a).

ANSWER: Paragraph 27 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 27.

28. Upon information and belief, Sandoz intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA product, with its proposed labeling, immediately and imminently upon approval of ANDA No. 090725.

ANSWER: Sandoz admits that it currently plans to engage in the manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA product, with its proposed labeling, after approval of ANDA No. 090725. The phrase "immediately and imminently upon approval of ANDA No. 090725" in paragraph 28 is vague and undefined, and therefore Sandoz denies the same. Sandoz denies any remaining allegations of paragraph 28.

29. Upon information and belief, immediately upon approval of ANDA No. 090725, Sandoz will infringe the '012 patent by making, using, offering to sell, selling, and/or importing Sandoz's ANDA product in the United States, and by actively inducing and contributing to others' direct infringement under 35 U.S.C. §§ 271(b) and (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 090725 shall be no earlier than the expiration of the '012 patent.

ANSWER: Paragraph 29 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 29.

30. Upon information and belief, the use of Sandoz's ANDA product constitutes a material part of at least one or more claims of the '012 patent; Sandoz knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '012 patent; and Sandoz's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Paragraph 30 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 30.

31. Upon information and belief, the offering to sell, sale, and/or importation of Sandoz's ANDA product would contributorily infringe one or more claims of the '012 patent.

ANSWER: Paragraph 31 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 31.

32. Upon information and belief, Sandoz had knowledge of the '012 patent and, by its promotional activities and package insert for Sandoz's ANDA product, knows or should know that it will actively aid and abet another's direct infringement of one or more claims of the '012 patent.

ANSWER: Paragraph 32 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 32.

33. Upon information and belief, the offering to sell, sale, and/or importation of Sandoz's ANDA product would actively induce infringement of one or more claims of the '012 patent.

ANSWER: Paragraph 33 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 33.

34. Unless Sandoz is enjoined from infringing the '012 patent, actively inducing infringement of the '012 patent, and/or contributing to the infringement by others of the '012 patent, Plaintiffs King Pharmaceuticals and Meridian will be substantially and irreparably harmed. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 34 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 34.

COUNT II
DECLARATORY JUDGMENT

35. Plaintiffs reallege and incorporate by reference paragraphs 1–34, above.

ANSWER: Sandoz repeats and incorporates its responses to paragraphs 1 through 34 above as if set forth fully herein.

36. Upon information and belief, if ANDA No. 090725 is approved, Sandoz's ANDA product will be distributed in the United States by Sandoz and its affiliates.

ANSWER: The phrase "Sandoz's ANDA product will be distributed in the United States by Sandoz and its affiliates" is vague and undefined, and therefore Sandoz denies the same. Sandoz denies any remaining allegations of paragraph 36.

37. Upon information and belief, Defendant knows that patients will use Sandoz's ANDA product in accordance with the labeling sought in ANDA No. 090725 and Defendant will therefore infringe one or more claims of the '012 patent.

ANSWER: Paragraph 37 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 37.

38. Upon information and belief, Defendant plans to begin marketing, selling, and offering to sell Sandoz's ANDA product immediately after FDA approves ANDA No. 090725. Such conduct will constitute infringement of one or more claims of the '012 patent under 35 U.S.C § 271.

ANSWER: Sandoz admits that it currently plans to begin marketing, selling, and/or offering to sell Sandoz's ANDA product after the FDA approves ANDA No. 090725. The phrase "immediately after FDA approves ANDA No. 090725" in paragraph 38 is vague and undefined, and therefore Sandoz denies the same. Sandoz denies any remaining allegations of paragraph 38.

39. Upon information and belief, Defendant's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Sandoz's ANDA product complained of herein will begin immediately after FDA approves ANDA No. 090725.

ANSWER: Paragraph 39 contains conclusions of law for which no response is required. Further, the phrases "infringing activity" and "immediately after FDA approves ANDA No. 090725" are vague and undefined, and therefore Sandoz denies the same. To the extent that a response is required, Sandoz denies any remaining allegations in paragraph 39.

40. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy concerning liability for the infringement of the '012 patent between Plaintiffs King Pharmaceuticals and Meridian and Defendant Sandoz.

ANSWER: Sandoz admits that there is a justiciable controversy between Sandoz and Plaintiffs concerning the '012 patent. Sandoz denies any remaining allegations of paragraph 40.

41. Plaintiffs Meridian and King Pharmaceuticals will be substantially and irreparably harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

ANSWER: Paragraph 41 contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz denies the allegations in paragraph 41.

PRAYER FOR RELIEF

Sandoz denies that Plaintiffs are entitled to any relief from the Court.

AFFIRMATIVE DEFENSES

Sandoz hereby raises the following affirmative defenses to the claims alleged in Plaintiffs' Complaint based on knowledge or information known or available at this time, or believed by Sandoz to be true at this time.

First Affirmative Defense

Sandoz has not and will not infringe, directly or indirectly, any valid and enforceable claim of the '012 patent, literally or under the doctrine of equivalents, by making, using, selling, offering for sale or importing any product into the United States that is the subject of Sandoz's ANDA No. 090725, nor do Sandoz's activities relating to the filing of ANDA No. 090725 result in infringement of any claim of the '012 patent.

Second Affirmative Defense

One or more claims of the '012 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§ 102, 103 and/or 112.

Third Affirmative Defense

The Complaint fails to state a claim upon which relief can be granted.

Sandoz reserves any other defenses, at law or in equity, that may be available now or may become available in the future based on discovery or any other factual development in this action.

COUNTERCLAIMS

As separate and independent Counterclaims against Plaintiffs King Pharmaceuticals, Inc. ("King Pharmaceuticals") and Meridian Medical Technologies, Inc. ("Meridian") (also collectively "Counterclaim Defendants"), Sandoz Inc. ("Sandoz") hereby alleges as follows:

THE PARTIES

1. King Pharmaceuticals admits that it is a corporation organized and existing under the laws of Tennessee with its principal place of business at 501 Fifth Street, Bristol, Tennessee 37620. (Dkt. 1, Complaint ¶2).

2. Meridian admits that it is a wholly-owned subsidiary of King Pharmaceuticals and that Meridian is organized and existing under the laws of Delaware with its principal place of business at 10240 Old Columbia Road, Columbia, Maryland 21046. (*Id.* at ¶3).

3. Sandoz is a corporation organized and existing under the laws of Colorado with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey.

4. Meridian claims to be the owner of U.S. Patent No. 7,449,012 B2 ("the '012 patent"). (*Id.* at ¶12).

5. Meridian claims to be the holder of approved New Drug Application No. 019-430 for the product which has the proprietary name EpiPen® (epinephrine) Auto-Injector 0.3/0.15 mg ("EpiPen® Auto-Injector"). (*Id.* at ¶4).

6. Sandoz filed Abbreviated New Drug Application No. 090725 ("ANDA No. 090725") with the U.S. Food and Drug Administration ("FDA"), seeking approval to market Sandoz's epinephrine injection in 0.3 mg/0.3 mL and 0.15 mg/0.3 mL dosage strengths ("Sandoz's ANDA product") that is the subject of ANDA No. 090725.

JURISDICTION AND VENUE

7. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has original jurisdiction over the subject matter of these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim Defendants at least because they have availed themselves of the rights and privileges of this forum by suing Sandoz in this judicial district.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391.

FIRST COUNTERCLAIM
(Declaratory Judgment of Non-Infringement of the '012 Patent)

11. Sandoz brings this action for declaratory judgment of non-infringement of the '012 patent under the laws of the United States, and in particular, 28 U.S.C. §§ 2201 and 2202, and restates paragraphs 1-10 of these Counterclaims as if set forth fully herein.

12. Plaintiffs/Counterclaim Defendants have alleged that Sandoz has infringed the '012 patent by filing ANDA No. 090725, and Sandoz has denied this allegation.

13. There is an actual, substantial and continuing justiciable case or controversy between the parties regarding infringement of the '012 patent.

14. Sandoz's filing of ANDA No. 090725 and Sandoz's ANDA product have not, and would not, infringe any valid and enforceable claim of the '012 patent, literally or under the doctrine of equivalents.

15. Sandoz is entitled to a judicial determination that Sandoz's filing of ANDA No. 090725 does not result in infringement of any valid and enforceable claim of the '012 patent and that Sandoz's ANDA product has not and would not infringe, directly or indirectly, any valid and enforceable claim of the '012 patent if made, used, sold, offered for sale, and/or imported into the United States.

SECOND COUNTERCLAIM
(Declaratory Judgment of Invalidity of the '012 Patent)

16. Sandoz brings this action for declaratory judgment of invalidity of the '012 patent under the laws of the United States, and in particular, 28 U.S.C. §§ 2201 and 2202, and restates paragraphs 1-10 of these Counterclaims as if set forth fully herein.

17. As evidenced by Plaintiffs' Complaint and Sandoz's Answer thereto, there is an actual, substantial and continuing justiciable case or controversy between the parties regarding the validity of the claims of the '012 patent.

18. Sandoz contends that one or more of the claims of the '012 patent are invalid for failure to comply with one or more of the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§ 102, 103 and/or 112.

19. Sandoz is entitled to a judicial determination that one or more claims of the '012 patent are invalid for failure to comply with the statutory provisions of 35 U.S.C. §§ 101, *et seq.*, including §§102, 103 and/or 112.

PRAYER FOR RELIEF

WHEREFORE, Sandoz respectfully prays for judgment as follows:

(i) Dismissal of Plaintiffs' Complaint with prejudice and entry of judgment in favor of Sandoz;

(ii) Judgment that the '012 patent claims were not infringed by Sandoz's filing of ANDA No. 090725, and that Sandoz's ANDA product that is the subject of ANDA No. 090725 has not and would not infringe, directly or indirectly, any claim of the '012 patent if made, used, sold, offered for sale, and/or imported into the United States;

(iii) Judgment that one or more claims of the '012 patent is invalid under one or more of the statutory provisions of Title 35 of the United States Code;

(iv) An award to Sandoz of its costs;

(v) Judgment that this is an exceptional case and an award to Sandoz of its reasonable attorneys' fees under 35 U.S.C. § 285 and/or the inherent discretion of the Court; and

(vi) Such further relief as this Court may deem just, equitable and appropriate.

Dated: September 13, 2010

Respectfully submitted,

By: /s/ Eric I. Abraham

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LOCAL CIVIL RULE 11.2 CERTIFICATION

I hereby certify pursuant to Local Civil Rule 11.2 that to the best of my knowledge, information and belief, the patents at issue in this action are at issue in the matter of King Pharmaceuticals, Inc. and Meridian Medical Technologies, Inc. v. Teva Parenteral Medicines, Inc. and Teva Pharmaceuticals USA, Inc. in the United States District Court, District of Delaware under Civil Action No. 09-652 (GMS).

/s/Eric I. Abraham
Eric I. Abraham

Dated: September 13, 2010

CERTIFICATE OF SERVICE

I hereby certify that on September 13, 2010, I served opposing counsel by e-mail and first class U.S. mail, and I electronically filed this ANSWER AND COUNTERCLAIMS with the Clerk of Court using the CM/ECF system which will also send notification of such filing to the following:

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